

# Exhibit FF

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

MITSUBISHI TANABE PHARMA  
CORPORATION, JANSSEN  
PHARMACEUTICALS, INC., JANSSEN  
PHARMACEUTICA NV, JANSSEN  
RESEARCH AND DEVELOPMENT, LLC,  
and CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

AUROBINDO PHARMA USA, INC., *et al.*,

Defendants.

Civil Action No. 17-5005 (PGS)(DEA)  
Civil Action No. 17-5135 (PGS)(DEA)  
Civil Action No. 17-5278 (PGS)(DEA)  
Civil Action No. 17-5302 (PGS)(DEA)  
Civil Action No. 17-7342 (PGS)(DEA)  
Civil Action No. 17-13130 (PGS)(DEA)  
Civil Action No. 18-292 (PGS)(DEA)

**DEFENDANTS' FIRST SET OF JOINT REQUESTS FOR  
THE PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-126)**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and the applicable Local Rules of the United States District Court for the District of New Jersey, defendants Auromundo Pharma USA, Inc. (“Auromundo”), InvaGen Pharmaceuticals, Inc. (“Invagen”), Macleods Pharma USA, Inc., and Macleods Pharmaceuticals, Ltd. (“Macleods”), MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (“MSN”), Laurus Labs Ltd. (“Laurus”), Indoco Remedies Ltd. (“Indoco”), Zydus Pharmaceuticals (USA) Inc. (“Zydus”), Sandoz Inc. (“Sandoz”), Teva Pharmaceuticals USA, Inc. (“Teva”), Apotex Inc. and Apotex Corp. (“Apotex”), Prinston Pharmaceutical Inc. (“Prinston”), Dr. Reddy’s Laboratories, Inc., Dr. Reddy’s Laboratories, Ltd. (“DRL”), Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited (“Hetero”), and Lupin Limited (“Lupin”) and Lupin Pharmaceuticals, Inc.<sup>1</sup>

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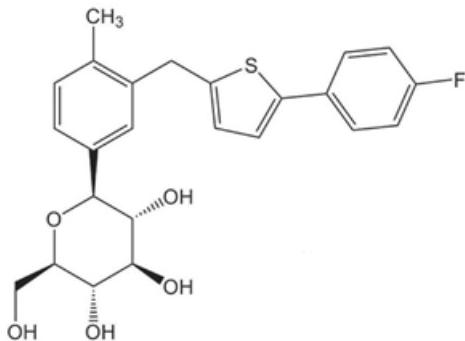
<sup>1</sup> As set forth in its Answer, Lupin Pharmaceuticals, Inc. contends that it is not a proper party to this action (*see, e.g.*, D.I. 9 ¶¶ 8, 33 (No. 3:18-cv-00292-PGS-DEA)).

(collectively, “Defendants”) request that plaintiffs Mitsubishi Tanabe Pharma Corp. (“MTPC”), Janssen Pharmaceuticals, Inc. (“JPI”), Janssen Pharmaceutica NV (“JNV”), Janssen Research and Development, LLC (“JRD”), and Cilag GmbH International (“Cilag”) (collectively, “Plaintiffs”) produce the documents and things requested herein at the offices of counsel for Defendants, or at an alternative location upon which the parties mutually agree, within thirty (30) days of the service of these requests in accordance with the provisions prescribed by such rules.

### **DEFINITIONS**

The following definitions shall apply:

1. The “‘202 patent” means U.S. Patent No. 8,513,202, U.S. Application No. 13/103,557, and all other applications and patents to which the ’202 patent claims priority, including any corrections, amendments, reissues, or reexaminations.
2. The “‘582 patent” means U.S. Patent No. 7,943,582, U.S. Application No. 11/987,670, and all other applications and patents to which the ’582 patent claims priority, including any corrections, amendments, reissues, or reexaminations.
3. The term “analyses” means tests, investigations, inspections, examinations, measurements, or experimental evaluations.
4. The terms “and” and “or” shall be interpreted either conjunctively or disjunctively, whichever makes the request more inclusive.
5. The term “ANDA” means Abbreviated New Drug Application.
6. The term “canagliflozin” means the compound referred to as, *inter alia*, (1S)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol or 1-( $\beta$ -D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienyl-methyl]benzene, or any other name or synonym for the same compound, in any form, the chemical structure of which can be represented by the following:



7. The term “canagliflozin product” means a drug product containing canagliflozin, in any form, as an active ingredient, whether or not in combination with other active ingredients.

8. The term “communication” means any transmittal of information (in the form of facts, ideas, inquiries or otherwise) by oral, written, telephonic, electronic, or radio frequency transmission, or by any other means and in any language, including but not limited to Japanese and/or English.

9. The term “Complaint” or “Complaints” means any Complaint filed by the plaintiffs in the above-captioned actions.

10. The term “concerning” means, in whole or in part, relating, constituting, containing, embodying, reflecting, describing, analyzing, identifying, mentioning, stating, referring directly or indirectly to, dealing with, or in any way pertaining to.

11. The term “Current Litigation” means the lawsuits captioned *Mitsubishi Tanabe Pharma Corp., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 17-5005 (PGS)(DEA); *Mitsubishi Tanabe Pharma Corp., et al. v. Prinston Pharmaceuticals, Inc. et al.*, Civil Action No. 17-5135 (PGS)(DEA); *Mitsubishi Tanabe, et al. v. Apotex*, Civil Action No. 17-5278 (PGS)(DEA); *Mitsubishi Tanabe Pharma Corp., et al. v. MSN Laboratories Private Ltd., et al.*, Civil Action No. 17-5302 (PGS)(DEA); *Mitsubishi Tanabe, et al. v. Prinston*, Civil Action No. 17-7342 (PGS)(DEA); *Mitsubishi Tanabe, et al. v. Macleods*, Civil Action No. 17-13130

(PGS)(DEA); and *Mitsubishi Tanabe, et al. v. Lupin Ltd.*, Civil Action No. 18-292 in the United States District Court for the District of New Jersey, any consolidation of such lawsuits, or any such amended caption or captions that should be later adopted.

12. The term “date” means the exact day, month, and year, if ascertainable, or, if not, your best approximation thereof.

13. The term “Defendants’ ANDAs” means ANDA No. 210386 submitted by Aurobindo; ANDA No. 210350 submitted by InvaGen; ANDA Nos. 210738 and 210380 submitted by Macleods; ANDA No. 210462 submitted by MSN; ANDA No. 210503 submitted by Laurus; ANDA Nos. 210311 and 210312 submitted by Indoco; ANDA Nos. 210541 and 210542 submitted by Zydus; ANDA Nos. 210297 and 210481 submitted by Sandoz; ANDA No. 210451 submitted by Teva; ANDA No. 210449 Apotex; ANDA No. 210514 submitted by Prinston; ANDA No. 210502 submitted by DRL; ANDA No. 210477 submitted by Hetero; ANDA Nos. 211103 and 211104 submitted by Lupin, to the FDA pursuant to 21 U.S.C. § 355(j).

14. The term “Defendants’ ANDA Products” means the drug products that are the subject of Defendants’ ANDAs.

15. The term “describe,” when used in relation to an act, event, instance, occasion, transaction, conversation, or communication, means: (1) to state the date and place thereof; (2) to identify the individual participants; (3) to summarize separately for each individual participant, his or her role, and what s/he said or did; and (4) to identify each document used or prepared in connection therewith or making any reference thereto.

16. The term “development” means conception, design, research, formulation, testing, evaluation, manufacture, production, use, or marketing, including any concepts rejected during the process of reaching the claimed inventions.

17. The term “document” is defined broadly to be given the full scope of that term contemplated in the Federal Rules of Civil Procedure and the Federal Rules of Evidence, and includes all non-identical copies of a document, all drafts of final documents, all other written, typed, printed, recorded or graphically portrayed matter in any form or embodiment, and all other data compilations from which information can be obtained and translated if necessary, that are or have been in your actual or constructive custody or control, regardless of the medium on which they are produced, reproduced, or stored (including computer programs and files containing any requested information), and any recording or writing, as these terms are defined in Federal Rule of Evidence 1001. Any document bearing marks, including initials, stamped initials, comments, or notations not part of the original text or photographic reproduction thereof, is a separate document.

18. The terms “each” and “any” mean any and all.

19. The term “FDA” means the U.S. Food and Drug Administration.

20. The term “identify,” when used with respect to a communication, means to state, to the extent known, the (i) means of communication (e.g., telephone call, meeting, etc.), (ii) date of the communication, (iii) subject matter of the communication, (iv) language of the communication, and (v) originator, recipient, and any other party to the communication.

21. The term “identify,” when used with respect to a document, means to state, to the extent known, the (i) type, (ii) subject matter, (iii) date, (iv) author(s), addressee(s), and recipient(s), (v) language of the document, and (vi) Bates number of the document.

22. The term “identify,” when used with respect to a person, means to state, to the extent known, the person’s full name, present or last known address, and when referring to a natural person, additionally, the occupation or business in which the person is engaged, and the person’s present or last employer and title or position.

23. The term “identify,” when used with respect to a thing, means to state, to the extent known, (i) any model or catalog number, (ii) any article or model name, (iii) any technical or promotional materials describing the article or its use, and (iv) the dates and locations of its production.

24. The term “IND” means Investigational New Drug Application.

25. The term “Invokamet®” means any dosage form of Plaintiffs’ drug products marketed under the trade name Invokamet® and subject to NDA No. 204353.

26. The term “Invokana®” means any dosage form of Plaintiffs’ drug products marketed under the trade name Invokana® and subject to NDA No. 204042.

27. The term “Named Inventor” means any individual listed as an inventor on the face of the Patents-in-Suit.

28. The term “NDA” means New Drug Application.

29. The term “Orange Book” means the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

30. The term “Patents-in-Suit” means, collectively, the ’202 patent and ’582 patent.

31. The term “person” means any individual, corporation, partnership, sole proprietorship, firm, board, joint venture, association, agency, authority, commission, or other entity.

32. The terms “Plaintiffs,” “you,” and “your” mean, collectively, MTPC, JPI, JNV, JRD, and Cilag, any of their predecessors, subsidiaries, domestic or foreign divisions, departments, parents, affiliates, present or former officers, directors, employees, agents, representatives, entities, acting in consort, joint-venture, or partnership relationship with them, and others acting on their behalf.

33. The term "prior art" encompasses all categories of documents, information, events, and circumstances described in 35 U.S.C. §§ 102-103.

34. The term "PTO" means the U.S. Patent and Trademark Office, including the Patent Trial and Appeals Board.

35. The term "thing" shall be construed under the broadest possible construction under the Federal Rules of Civil Procedure.

36. The terms "United States" and "U.S." means the fifty states, the District of Columbia, and Puerto Rico.

37. The use of a verb in any tense shall be construed as the use of the verb in all other tenses, and the singular form shall be deemed to include the plural and vice-versa.

### **INSTRUCTIONS**

The following instructions shall apply:

1. The form of your responses to the following requests shall comply with the applicable Federal Rules of Civil Procedure and the U.S. District Court for the District of New Jersey's Local Civil Rules.

2. You are to produce all responsive documents and things in the same file or other organizational environment in which they are kept in the usual course of business. For example, documents that are part of a file or other grouping should be physically produced together in the same order or manner of arrangement as they are maintained in that file or grouping.

Alternatively, as to each document or thing produced, you shall identify the request and, where applicable, the Interrogatory in response to which the document or thing is being produced.

Where a document or thing exists in hard copy and electronic format you shall produce both the hard and the electronic copy.

3. You shall keep and produce a record of the source of each document and thing produced. This shall include the name and location of the file or other organizational environment where each document or thing was located and the name of the person, group, or department having possession, custody, or control of each document or thing.

4. You shall ensure that all responsive documents and things are preserved for this litigation, and that no responsive electronically stored documents or things in your possession, custody, or control are erased, deleted, or destroyed.

5. These requests seek all responsive documents and things in their original language and, if any documents' original language is not English, these requests also seek all English-language translations for those documents.

6. If you object to any request in part, then you should identify the objected-to part of the Request and produce documents and things responsive to all parts of the request to which you do not object.

7. If you claim that a request is vague and/or ambiguous, identify the particular words, terms, or phrases that you contend make the request vague and/or ambiguous, and specify the meaning you attribute to those words, terms, or phrases for purposes of your response thereto.

8. If you decline to produce any document, or portion thereof, in response to any request based on a claim of privilege or immunity, then for each document, or portion thereof, withheld, state the following within a privilege log: (a) the date the information was created or communicated; (b) the author(s) or speaker(s); (c) all recipients; (d) the employer and position for each author, speaker, or recipient, including whether that person is an attorney or patent agent; (e) the general subject matter of the information; and (f) the type of privilege or protection claimed.

9. Any redacted document should be clearly stamped with the word “REDACTED” or “PRIVILEGED,” and the portions redacted should be clearly indicated.

10. If any document or thing requested herein was, but no longer is, in your possession, custody, or control, state whether it has been lost, destroyed, transferred, is missing, or has otherwise been disposed of, and explain the circumstances surrounding the disposition of the document or thing and the date that such disposal occurred.

11. These requests shall include information acquired or identified up to the date that you respond to them and shall be deemed to be continuing. Therefore, Plaintiffs shall promptly produce, as supplemental responses to these requests in accordance with Federal Rule of Civil Procedure 26(e), any additional information that Plaintiffs identify, acquire, or become aware of up to and including the time of trial.

12. If no documents or things are responsive to a particular request, then state that you have no responsive documents or things in your possession, custody, or control.

13. Unless specifically limited in a particular request, these requests are not limited as to time or location, and therefore the documents and things produced in response should include documents and things originating at any time, whether in this or any other country.

14. Electronically stored information shall be produced in accordance with any ESI stipulation ordered in the Current Litigation

PLEASE TAKE NOTICE that these requests are submitted for the purposes of discovery and are not to be construed as waiving any objections to the introduction of evidence on subjects covered by these requests that may be made at trial or as an admission at trial of the relevance or materiality of the matters covered by these requests.

## **REQUESTS FOR PRODUCTION**

### **REQUEST NO. 1:**

All documents, communications, and things concerning the research, development, and/or testing of any product allegedly covered by or described in the Patents-in-Suit, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and all test data, including preclinical and clinical testing data, animal modeling data, experimental results, data obtained by analytical techniques, and all conclusions based thereon.

### **REQUEST NO. 2:**

All documents, communications, and things concerning the Patents-in-Suit, including, without limitation, all documents and communications concerning:

- (a) the patentability of any alleged invention or subject matter claimed or disclosed therein, including all correspondence, memoranda, presentations, studies, prior-art searches, the results of any prior-art searches, and any report based on the prior-art searches;
- (b) the inventorship or any alleged invention or subject matter claimed or disclosed therein, including all documents concerning the contribution of each Named Inventor to any such invention;
- (c) the conception, development, and reduction to practice of any alleged invention or subject matter claimed or disclosed therein, including all invention disclosures, laboratory notebook entries, reports, memoranda, analyses, and meeting minutes related thereto;
- (d) the preparation of the applications that resulted in the Patents-in-Suit and any domestic and foreign patent applications related thereto, including all documents reviewed, considered, relied upon, or referenced by the patent attorney(s) or agent(s), Named Inventors, or anyone else involved in preparing such applications;
- (e) the prosecution of the applications that resulted in the Patents-in-Suit and any domestic and foreign patent applications related thereto, including all file wrappers and prosecution histories, and all applications, documents, and communications sent to or received from any third party, including the PTO, the Named Inventors, any patent agent or attorney, any prior-art researcher, and any person who authored a declaration submitted under 37 C.F.R. 1.132;
- (f) any opposition (including oppositions to foreign counterparts), litigation, reissues, reexaminations, *inter partes* review, interferences, or any other proceedings relating to the validity, enforceability, infringement, and/or extension of the Patents-in-Suit;
- (g) Plaintiffs' purchase, licensing, and/or acquisition of any ownership interest in or other rights to the Patents-in-Suit, including documents sufficient to show the current ownership of the Patents-in-Suit, documents sufficient to identify all persons involved

in the acquisition of any interest in or other rights to the Patents-in-Suit by Plaintiffs, and documents and communications concerning any due diligence performed with respect to such acquisition, including any valuations of the Patents-in-Suit; and

- (h) Plaintiffs' decision(s) to list, and to continue listing, the Patents-in-Suit in the Orange Book.

**REQUEST NO. 3:**

All documents authored by any Named Inventor concerning the subject matter of the Patents-in-Suit.

**REQUEST NO. 4:**

All documents and communications relating to the identity of individuals who allegedly conceived of, and/or reduced to practice or assisted in the reduction to practice of, the inventions or subject matter claimed in the Patents-in-Suit.

**REQUEST NO. 5:**

All documents and communications relating to the contributions of any of the Named Inventors and other individuals to any invention of the claims of the Patents-in-Suit.

**REQUEST NO. 6:**

All communications between and among the Named Inventors pertaining to the conception and/or reduction to practice of the inventions of the claims of the Patents-in-Suit.

**REQUEST NO. 7:**

All communications between and among the Named Inventors pertaining to the subject matter of the claims of the Patents-in-Suit.

**REQUEST NO. 8:**

All documents and communications that constitute, refer, or relate to the first disclosure to anyone of the subject matter claimed in the Patents-in-Suit.

**REQUEST NO. 9:**

All documents and communications that refer to or relate to the first use of a product embodying the subject matter claimed in the Patents-in-Suit.

**REQUEST NO. 10:**

All document or thing supporting, refuting, or relating to your contention that you are entitled to injunctive relief.

**REQUEST NO. 11:**

Documents and things sufficient to identify the first time each of the methods claimed in the Patents-in-Suit were first performed: (a) in a research setting; (b) privately; and (c) publicly.

**REQUEST NO. 12:**

Documents and things sufficient to identify the first manufacture, first sale, first offer for sale, first importation, and first public disclosure of any canagliflozin product.

**REQUEST NO. 13:**

Documents and things sufficient to identify each person who was or is involved in the sale or purchase of Invokana® or Invokamet®.

**REQUEST NO. 14:**

Documents and things sufficient to identify each person who was or is involved in the marketing or offering for sale of Invokana® or Invokamet®.

**REQUEST NO. 15:**

All documents and communications concerning the validity of any claim of the Patents-in-Suit or the enforceability of the Patents-in-Suit, including, without limitation, all correspondence, memoranda, presentations, studies, prior-art searches, and the results of any prior-art searches.

**REQUEST NO. 16:**

All prior art relating to any Patent-in-Suit (whether or not such prior art was disclosed to the PTO), including, without limitation, (1) any prior art identified during any prior-art search conducted by Plaintiffs or on its behalf; (2) any prior art identified or made known to Plaintiffs by any third party; (3) all internal documents and communications concerning any prior art identified or made known to the Plaintiffs; and (4) any prior art identified by any party in the Current Litigation.

**REQUEST NO. 17:**

All publications and manuscripts prepared by Plaintiffs for publication (and all published versions, if applicable) concerning canagliflozin, whether such publications and manuscripts were submitted for publication in this or any other country, including drafts and submissions thereof.

**REQUEST NO. 18:**

All documents, communications, and things relating to the first publication of any clinical trials concerning canagliflozin.

**REQUEST NO. 19:**

All documents, communications, and things relating to any examples, including Examples 1 and 2, in the Patents-in-Suit, including, without limitation, data (including records of clinical data or analyses of clinical data), reports, protocols, analyses, analytical data, and summaries for each example, and laboratory notebooks.

**REQUEST NO. 20:**

All documents that Plaintiffs contend evince the skills and/or qualifications of a person of ordinary skill in the art pertaining to the Patents-in-Suit, including, without limitation, (1) the educational level of the Named Inventors; (2) the type of problems encountered in the art; (3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field.

**REQUEST NO. 21:**

All documents that Plaintiffs contend evince the lack of skills and/or qualifications of one failing to meet a person of ordinary skill in the art pertaining to the Patents-in-Suit, including, without limitation, (1) the educational level of the Named Inventors; (2) the type of problems encountered in the art; (3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field.

**REQUEST NO. 22:**

Documents and things sufficient to identify all persons involved in any decisions or discussions relating to whether to seek patent claims covering the subject matter of any of the claims of the Patents-in-Suit, including any communications between Plaintiffs and the Named Inventors or any attorney for Plaintiffs and the Named Inventors.

**REQUEST NO. 23:**

Documents and things sufficient to identify each person who was or is involved in the research and development of any of Plaintiffs' canagliflozin products.

**REQUEST NO. 24:**

All prior art submitted to the PTO during prosecution of the Patents-in-Suit.

**REQUEST NO. 25:**

All references cited, discussed, or otherwise disclosed in the specification(s) of the Patents-in-Suit.

**REQUEST NO. 26:**

All documents, communications, and things supporting, refuting, and/or otherwise relating to any secondary considerations (or objective indicia) of nonobviousness concerning the subject matter of the Patents-in-Suit.

**REQUEST NO. 27:**

All documents, communications, and things supporting, refuting, and/or otherwise relating to any unexpected results achieved by practicing any of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 28:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of a 100mg dose of canagliflozin.

**REQUEST NO. 29:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of a 300mg dose of canagliflozin.

**REQUEST NO. 30:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of a 50mg dose of canagliflozin and 500mg dose of metformin.

**REQUEST NO. 31:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of a 50mg dose of canagliflozin and 1000mg dose of metformin.

**REQUEST NO. 32:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of a 150mg dose of canagliflozin and 500mg dose of metformin.

**REQUEST NO. 33:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of a 150mg dose of canagliflozin and 1000mg dose of metformin.

**REQUEST NO. 34:**

All documents, communications, and things concerning any purported unexpected benefits pertaining to the administration of about 0.01mg/kg to about 100mg/kg body weight of canagliflozin.

**REQUEST NO. 35:**

All documents, communications, and things supporting, refuting, or otherwise relating to any unexpected properties of any of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 36:**

All documents, communications, and things supporting, refuting, or otherwise relating to any copying by anyone of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 37:**

All documents, communications, and things supporting, refuting, or otherwise relating to any criticism by anyone of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 38:**

All documents, communications, and things supporting, refuting, or otherwise relating to any skepticism by anyone of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 39:**

All documents, communications, and things supporting, refuting, or otherwise relating to any long-felt, unmet need for any of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 40:**

All documents, communications, and things supporting, refuting, or otherwise relating to any commercial success by any embodiments of any of the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 41:**

All documents, communications, and things supporting, refuting, or otherwise relating to any teaching away from the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 42:**

All documents, communications, and things supporting, refuting, or otherwise relating to the failure of others regarding the subject matter disclosed in the Patents-in-Suit.

**REQUEST NO. 43:**

All documents that Plaintiffs relied upon or intends to rely upon for purposes of claim construction in the Current Litigation.

**REQUEST NO. 44:**

All documents and communications concerning any test and/or experiment referenced in the Patents-in-Suit, and the results obtained from those tests and/or experiments, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto, as well as all information regarding the instrumentation used to carry out such testing.

**REQUEST NO. 45:**

All documents and communications concerning the pharmaceutical composition of Invokana® and/or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 46:**

All documents and communications concerning any composition testing on any solid form of canagliflozin, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 47:**

All documents and communications concerning the formulation of Invokana® and/or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 48:**

All documents and communications concerning any formulation testing on any form of canagliflozin, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto, as well as all information regarding the instrumentation used to carry out such testing.

**REQUEST NO. 49:**

All documents and communications concerning the dosage(s) used or considered for Invokana® or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto, as well as all information regarding the instrumentation used to carry out such testing.

**REQUEST NO. 50:**

All documents and communications concerning any dosage testing on any form of canagliflozin, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 51:**

All documents and communications concerning the physical properties of Invokana® and/or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 52:**

All documents and communications concerning the physical properties of any canagliflozin product, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 53:**

All documents and communications concerning the physical properties of any form of canagliflozin, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 54:**

All documents, communications, and things concerning any infra-red spectra for Invokana® and/or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 55:**

All documents, communications, and things concerning any infra-red testing, including in mineral oil, on any form of canagliflozin and/or on any canagliflozin product, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 56:**

All documents, communications, and things concerning any X-ray powder diffraction data and pattern(s) for Invokana® and/or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto, as well as all information regarding the instrumentation used to carry out such testing.

**REQUEST NO. 57:**

All documents, communications, and things concerning any X-ray powder diffraction testing on any form of canagliflozin and/or on any canagliflozin product, including, without

limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 58:**

[REDACTED]

**REQUEST NO. 59:**

[REDACTED]

**REQUEST NO. 60:**

All documents and communications concerning the formation, preparation, conversion, stability, detection, characterization, analysis and study of any hydrate or non-hydrate form of canagliflozin, including but not limiting to any hemihydrate of canagliflozin referred to in the Patents-in-Suit.

**REQUEST NO. 61:**

All documents and communications concerning the formation, preparation, conversion, stability, detection, characterization, analysis and study of any form of canagliflozin in the active pharmaceutical ingredient of Invokana® and/or Invokamet®.

**REQUEST NO. 62:**

All documents and communications concerning the bioequivalency of Invokana® and/or Invokamet® relative to any other canagliflozin product, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 63:**

All documents and communications concerning the bioequivalency of any canagliflozin product relative to any other canagliflozin product, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 64:**

All documents and communications concerning any treatment effects of Invokana® and/or Invokamet®, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 65:**

All documents and communications concerning any treatment effects of any form of canagliflozin, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 66:**

All documents and communications relating to any off-label prescribing of any canagliflozin product, including Invokana® and Invokamet®.

**REQUEST NO. 67:**

All documents and communications relating to any non-prescribed use of any canagliflozin product, including Invokana® and Invokamet®.

**REQUEST NO. 68:**

All documents and communications concerning administration of canagliflozin, in any form, for the treatment of diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, and/or hypertension, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 69:**

All documents, communications, and things concerning any comparison testing or analysis between different dosages of canagliflozin, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, test methods, and test data related thereto.

**REQUEST NO. 70:**

All documents, communications, and things concerning any comparative testing or analysis between Invokana® and/or Invokamet® and any canagliflozin product, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, test methods, and test data related thereto.

**REQUEST NO. 71:**

All licenses or other agreements, assignments, transfers, liens, or other retention of rights concerning canagliflozin or any canagliflozin product, including, but not limited to, Invokana® and Invokamet®.

**REQUEST NO. 72:**

All documents and communications concerning the assignment or ownership of the Patents-in-Suit, including, but not limited to, all assignments, inter- or intra-company transfers, and agreements related thereto.

**REQUEST NO. 73:**

All documents and communications relating to agreements with any company or companies for the development, sale, marketing, or promotion of any canagliflozin product, including, but not limited to, any agreements and drafts thereof between the individual Plaintiffs or their predecessors or any other company that sells, develops, or manufactures Invokana® and/or Invokamet®.

**REQUEST NO. 74:**

All employee, consulting, or other agreements relating to any Named Inventor of any of the Patents-in-Suit, or non-United States counterpart of any of the Patents-in-Suit.

**REQUEST NO. 75:**

Documents sufficient to show the relationship between MTPC, JPI, JNV, JRD, and Cilag, including any of their affiliates or predecessor, including any agreements, assignments, assignments, transfers, liens, or other retention of rights concerning canagliflozin or any canagliflozin product, including, but not limited to, Invokana® and Invokamet®.

**REQUEST NO. 76:**

All documents and communications between and among MTPC, JPI, JNV, JRD, and/or Cilag pertaining to any licensing of the Patents-in-Suit.

**REQUEST NO. 77:**

All documents and communications between and among MTPC, JPI, JNV, JRD, and/or Cilag pertaining to any licensing of any canagliflozin product, including Invokana® and Invokamet®.

**REQUEST NO. 78:**

All documents and communications between and among MTPC, JPI, JNV, JRD, and/or Cilag pertaining to any due diligence associated with the licensing of any canagliflozin product or the Patents-in-Suit.

**REQUEST NO. 79:**

Documents sufficient to show the existence, if any, of any joint defense agreement or common interest agreement between and among MTPC, JPI, JNV, JRD, and/or Cilag pertaining to any canagliflozin product.

**REQUEST NO. 80:**

All documents and communications concerning the administration of any canagliflozin product in clinical trials, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and test data related thereto.

**REQUEST NO. 81:**

NDA Nos. 204042 and 204353 and all documents, communications, and things concerning NDA Nos. 204042 and 204353, including, without limitation:

- (a) all documents and communications concerning all drafts, versions, submissions, revisions, updates, amendments, and supplements thereof;
- (b) all documents and communications concerning the development, preparation, submissions, approval, and maintenance thereof; and
- (c) all communications to or with any third party, including the FDA, related thereto.

**REQUEST NO. 82:**

IND Nos. 76,479 and 110,545 and all documents, communications, and things concerning IND Nos. 76,479 and 110,545, including, without limitation:

- (a) all documents and communications concerning all drafts, versions, submissions, revisions, updates, amendments, and supplements thereof;
- (b) all documents and communications concerning the development, preparation, submissions, approval, and maintenance thereof; and
- (c) all communications to or with any third party, including the FDA, related thereto, including any pre-IND communications such as a pre-IND briefing package or pre-IND meeting minutes.

**REQUEST NO. 83:**

All documents and communications concerning the development and/or commercialization of Invokana® and/or Invokamet®, including, without limitation, any communications or correspondence relating to any decisions to develop or commercialize a canagliflozin product.

**REQUEST NO. 84:**

All documents and communications concerning the manufacture of any canagliflozin product, including, without limitation, all documents and communications relating to any decisions to manufacture Invokana® and/or Invokamet®.

**REQUEST NO. 85:**

Documents and things sufficient to identify each person who was or is involved in the manufacturing of any canagliflozin product.

**REQUEST NO. 86:**

All documents and things concerning or discussing Citizen Petitions or MTPC's, JPI's, JNV's, JRD's, and/or Cilag's intent to file Citizen Petitions relating to any canagliflozin product, including, but not limited to, Invokana®, Invokamet®, or Defendants' ANDA Products.

**REQUEST NO. 87:**

All documents and things that compare the products of NDA Nos. 204042 and/or 204353 to any claim of any of the Patents-in-Suit.

**REQUEST NO. 88:**

All documents, communications, and things comparing Invokana® and/or Invokamet® to other canagliflozin products, including all documents and communications concerning:

- (a) the research, development, and testing thereof, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, and all test data, including preclinical testing data, animal modeling data, experimental results, and all conclusions based thereon;
- (b) any comparison of the similarities or differences between Invokana® or Invokamet® and Defendants' ANDA Products; and
- (c) any comparison of the similarities or differences between Invokana® or Invokamet® and any other canagliflozin formulation.

**REQUEST NO. 89:**

All documents and communications concerning Defendants' ANDAs or Defendants' ANDA Products, including, without limitation, all evaluations, analyses, studies, and opinions related thereto.

**REQUEST NO. 90:**

All documents and communications relating to whether Defendants' ANDA Products do or do not infringe any claim of the Patents-in-Suit.

**REQUEST NO. 91:**

All documents and communications supporting, refuting, or otherwise relating to Plaintiffs' allegations and causes of action set forth in the Plaintiffs' Complaints, including its infringement allegations.

**REQUEST NO. 92:**

All documents and communications concerning Plaintiffs' decision to file the Plaintiffs' Complaints, including, without limitation, Plaintiffs' pre-suit investigation concerning Defendants' ANDAs and Defendants' ANDA Products.

**REQUEST NO. 93:**

Documents sufficient to show the costs associated with marketing or promoting Invokana® and/or Invokamet®, including the costs of the sales force, detailing, product sampling, and all other promotional costs associated with Invokana® and/or Invokamet®.

**REQUEST NO. 94:**

Documents sufficient to show the marketing, advertising, or promotion for Invokana® and/or Invokamet®, including, without limitation, any marketing plans, advertising plans, promotional programs, or strategies.

**REQUEST NO. 95:**

Documents sufficient to show the sales, revenue, or profits for Invokana® and/or Invokamet®, including but not limited to any group purchases, from the launch of Invokana® and/or Invokamet® to the present.

**REQUEST NO. 96:**

Documents sufficient to show any market analysis by or on behalf of Plaintiffs relating to Invokana® and/or Invokamet®.

**REQUEST NO. 97:**

Documents sufficient to show cost data (including unit costs), sales data, profit data, and market share data, including rebate, chargeback, and adjustment data, given on a monthly basis from the launch of Invokana® and/or Invokamet® to the present.

**REQUEST NO. 98:**

All documents sufficient to identify the recipients of educational funding for Invokana® and/or Invokamet® and the amounts of such funding received, including, but not limited to grants provided to doctors, medical institutions, or associations for symposia, speaker programs, and other educational programs.

**REQUEST NO. 99:**

All documents and communications relating to the effect of the entry of any generic canagliflozin product in the United States and any underlying documents that set forth the basis for the effect.

**REQUEST NO. 100:**

All documents and communications relating to the release or plans to release any authorized generic version of Invokana®, Invokamet®, or any canagliflozin product, including, but not limited to, any agreements regarding same.

**REQUEST NO. 101:**

Documents sufficient to show the forecast or projection for sales, revenue, and profit for Invokana® and/or Invokamet® in the United States from launch to present.

**REQUEST NO. 102:**

Documents sufficient to show the total revenue each year from sales of any products under the brand name Invokana® and/or Invokamet® on a monthly basis.

**REQUEST NO. 103:**

All press releases, publications, advertising, marketing, and promotional materials, and documents describing promotional efforts, authored by or on behalf of Plaintiffs concerning the Patents-in-Suit, Invokana®, Invokamet®, or any ANDA referencing Invokana® and/or Invokamet®.

**REQUEST NO. 104:**

All documents and communications concerning the strategies for the life cycle management of Invokana®, Invokamet®, or any canagliflozin product.

**REQUEST NO. 105:**

All documents concerning the nexus between any secondary considerations of Plaintiffs' Invokana® and/or Invokamet® products and any claims of the Patents-in-Suit.

**REQUEST NO. 106:**

All documents concerning physician or customer feedback, surveys, physician or customer preferences, or any other information as to why physicians or customers purchase Invokana® and/or Invokamet®.

**REQUEST NO. 107:**

All documents pertaining to any strategy for setting the price of Invokana® and/or Invokamet®.

**REQUEST NO. 108:**

All documents that Plaintiffs intend to offer or introduce at trial or any hearing in this action.

**REQUEST NO. 109:**

All documents referred to in any Fed. R. Civ. Pro. 26(a) disclosure served by Plaintiffs in this action.

**REQUEST NO. 110:**

All documents and things reviewed, relied upon, or considered by any expert for Plaintiffs in the Current Litigation.

**REQUEST NO. 111:**

Documents and communications sufficient to identify every instance any expert hired by Plaintiffs was subject to a *Daubert* challenge.

**REQUEST NO. 112:**

The current curriculum vitae, resume, biography, or equivalent document for each Named Inventor, other individual identified in Plaintiffs' disclosures under Fed. R. Civ. Pro. 26(a), or expert for Plaintiffs.

**REQUEST NO. 113:**

All deposition transcripts of any expert for Plaintiffs or Named Inventors pertaining to Canagliflozin and/or the Patents-in-Suit.

**REQUEST NO. 114:**

All documents referred to or relied upon by Plaintiffs in responding to any interrogatory or requests for admission served by Defendants.

**REQUEST NO. 115:**

All documents and communications relating to any agreement between one or more Plaintiffs and any third party relating to the settlement of any claim of infringement of any Patent-in-Suit, including all proposed and actual agreements, and all documents and communications relating to any negotiations of such agreements.

**REQUEST NO. 116:**

One hundred (100) canagliflozin tablets 100 mg marketed under the tradename Invokana® and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately, which tablets expire no earlier than April 12, 2019.

**REQUEST NO. 117:**

One hundred (100) canagliflozin tablets 300 mg marketed under the tradename Invokana® and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately, which tablets expire no earlier than April 12, 2019.

**REQUEST NO. 118:**

One hundred (100) canagliflozin/metformin hydrochloride tablets 50 mg/500 mg marketed under the tradename Invokamet® and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately, which tablets expire no earlier than April 12, 2019.

**REQUEST NO. 119:**

One hundred (100) canagliflozin/metformin hydrochloride tablets 50 mg/1 g marketed under the trade name Invokamet® and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately, which tablets expire no earlier than April 12, 2019.

**REQUEST NO. 120:**

One hundred (100) canagliflozin/metformin hydrochloride tablets 150 mg/500 mg marketed under the trade name Invokamet® and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately, which tablets expire no earlier than April 12, 2019.

**REQUEST NO. 121:**

One hundred (100) canagliflozin/metformin hydrochloride tablets 150 mg/1 g marketed under the trade name Invokamet® and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately, which tablets expire no earlier than April 12, 2019.

**REQUEST NO. 122:**

[REDACTED] and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately.

**REQUEST NO. 123:**

[REDACTED] and the corresponding manufacturing and analytical records and instructions for storage, to each defendant group separately.

**REQUEST NO. 124:**

Each document and thing relating to the listing and/or delisting of the Patents-in-Suit in the FDA's Orange Book in connection with Invokana® and/or Invokamet®.

**REQUEST NO. 125:**

Each document and thing relating to labeling or proposed labeling for Invokana® and/or Invokamet®.

**REQUEST NO. 126:**

Each document and thing related to any compensation received by each named inventor of the Patents-in-Suit for their work related to one or more of the Patents-in-Suit.

March 16, 2018

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on March 16, 2018, true and correct copies of the foregoing document were caused to be served via electronic mail on the following counsel for Plaintiffs:

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